

REMARKS

In the final Office Action mailed on November 26, 2007, the Examiner rejected claims 34-36, 38-45, 47-49, 52-55, and 57-60 under 35 U.S.C. § 101 for allegedly claiming an invention directed to non-statutory matter; rejected claims 34-36, 38-45, 47-49, 52-55, and 57-60 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite; rejected claims 34-36, 38-45, 47-49, 52-54, and 57-60 under 35 U.S.C. § 102(b) as allegedly being anticipated by O'Connor (U.S. Patent No. 5,450,860); rejected claims 34-36, 38-45, 47-49, and 58-60 under 35 U.S.C. § 102(e) as allegedly being anticipated by Fleischman et al. (U.S. Patent No. 6,132,438); rejected claims 34-36, 38-45, 47-49, 52-55, 57, 59, and 60 under 35 U.S.C. § 102(e) as allegedly being anticipated by Melvin (U.S. Patent No. 5,957,977); and rejected claim 55 under 35 U.S.C. § 102(b) as allegedly being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over O'Connor (or claim 57 of Fleischman et al.). The Examiner made the rejections final.

By this amendment, Applicant amends claims 34 and 40-42, adds new claims 80-91, and cancels claims 15-33, 58, and 63-79 without prejudice or disclaimer. Applicant reserves the right to present the subject matter of the cancelled claims at a later date. Claims 34-36, 38-45, 47-55, 57, 59-60, and 80-91 are currently pending. Of these claims, claims 50-51 were withdrawn from further prosecution. Of the examined claims, claims 34, 40, 41, and 42 are independent.

35 U.S.C. § 101 Rejection

Although Applicant does not necessarily agree that claims 34-36, 38-45, 47-49, 52-55, and 57-60 are claiming inventions directed to non-statutory subject matter,

Applicant has amended claims 34 and 40-42 as suggested by the Examiner.

Accordingly, Applicant respectfully submits that claims 34-36, 38-45, 47-49, 52-55, and 57-60 do not claim inventions directed to non-statutory subject matter. Applicant therefore requests the reconsideration and withdrawal of the Section 101 rejection of claims 34-36, 38-45, 47-49, 52-55, and 57-60.

35 U.S.C. § 112 Rejection

Although Applicant does not necessarily agree that claims 34-36, 38-55, 47-49, 52-55, and 57-60 are indefinite, as alleged by the Examiner, Applicant has nonetheless amended claims 34 and 40-42 to incorporate the Examiner's suggestions set forth on page 3 of the Office Action. Accordingly, Applicant respectfully submits that claims 34-36, 38-55, 47-49, 52-55, and 57-60 are not indefinite. Applicant therefore requests the reconsideration and withdrawal of the Section 112, second paragraph, rejection of claims 34-36, 38-55, 47-49, 52-55, and 57-60.

Section 102 Rejections

Applicant respectfully traverses each of the Examiner's Section 102 rejections as set forth below. Each of amended claims 34, 40, 41, and 42 recite a device comprising, among other things, a plurality of members and a connector having a first end, a second end, and "a structure for connecting the connector to one of the plurality of members, the structure being disposed proximate one of the first and second ends, wherein one of the plurality of members includes a recess for receiving the structure, the recess corresponding in one of shape and size to the structure, and wherein the structure

includes a cross-sectional dimension that is different than a cross-sectional dimension of the connector.”

35 U.S.C. § 102(b) Rejection Over O'Connor

Applicant respectfully traverses the Section 102(b) rejection of claims 34-36, 38-45, 47-49, 52-54, and 57-60 over O'Connor.

O'Connor discloses a device 10 and method for repairing heart valves. See, for example, Abstract. The O'Connor device 10 includes a ligament 12 having ends 14 and 20. See, for example, Fig. 1. As shown in Fig. 1, some embodiments of ligament 12 may have a first surgical needle 16 attached to end 14 and a second surgical needle 18 attached to end 20. Other embodiments of ligament 12 may have a surgical needle attached to one end and a stop device 72 or 76 attached to the ligament's other end. See, for example, Figs. 16 and 17. O'Connor further discloses the use of mattress sutures 40/42 placed in tissue 44 of a valve's annulus. See Fig. 3. Mattress sutures 40/42 “act as both markers for the device ends and tie-down sutures to hold the device in place . . . and may include pledgets [48] to protect the tissue from tearing.” See col. 7, lines 35-40.

In the Office Action, the Examiner alleges that the ligament 12 and sutures/pledgets 40, 42, and 48 correspond to the claimed connector and plurality of members, respectively. See Office Action at page 3. Applicant respectfully disagrees. Even assuming that ligament 12 and sutures/pledgets 40, 42, and 48 and structure of device 10 meet the other recitations of claims 34, 40, 41, and 42, which Applicant does not concede, O'Connor does not disclose, teach, or otherwise suggest that ligament 12 includes a structure for connecting the ligament 12 to one of the sutures/pledgets 40,

42, and 48, wherein the structure includes a cross-sectional dimension that is different than a cross-sectional dimension of the ligament 12, as required by each of independent claims 34, 40, 41, and 42. Additionally, O'Connor does not disclose, teach, or otherwise suggest that one of the sutures/pledgets 40, 42, and 48 includes a recess for receiving the claimed structure, wherein the recess corresponds in one of shape and size to the structure, as also required by each of independent claims 34, 40, 41, and 42. Accordingly, O'Connor fails to disclose, teach, or otherwise suggest each and every limitation of independent claims 34, 40, 41, and 42.

For at least these reasons, Applicant respectfully requests the reconsideration and withdrawal of the rejection of claims 34-36, 38-45, 47-49, 52-54, and 57-60 over O'Connor.

35 U.S.C. § 102(e) Rejection Over Fleischman et al.

Applicant respectfully traverses the Section 102(e) rejection of claims 34-36, 38-45, 47-49, and 58-60 over Fleischman et al.

Fleischman et al. discloses a number of methods and devices for installing stasis reducing means in body tissue. For the purposes of this response, Applicant understands that the Examiner has relied solely on the devices disclosed in Figs. 31A-C and 32B. See Office Action at pages 4-5. If Applicant's understanding is incorrect, the Examiner is invited to telephone the undersigned as soon as possible.

Figures 31A-C of Fleischman et al. show a mechanism which creates a purse-string-like constriction around the interior surface of an atrial appendage 16 or 17. "This arrangement enables pulling of adjacent walls together, thus forming a tightened sack in which the pouch of the appendage is separated from the remainder of the atrium." See

col. 13, lines 12-15. The disclosed mechanism may include sutures 126 and expandable anchors 116 (Figs. 31A-C) or 120 (Fig. 32B).

In the Office Action, the Examiner contends that the disclosed sutures 126 and expandable anchors 116/120 correspond to the claimed connector and plurality of members, respectively. See Office Action at pages 4-5. Applicant respectfully disagrees. Even assuming that sutures 126 and expandable anchors 116/120 and structure of the disclosed Fleischman et al. device meet the other recitations of claims 34, 40, 41, and 42, which Applicant does not concede, Fleischman et al. does not disclose, teach, or otherwise suggest that any of sutures 126 includes a structure for connecting the sutures 126 to one of the expandable anchors 116/120, wherein the structure includes a cross-sectional dimension that is different than a cross-sectional dimension of the sutures 126, as required by each of independent claims 34, 40, 41, and 42. Additionally, Fleischman et al. does not disclose, teach, or otherwise suggest that one of the expandable anchors 116/120 includes a recess for receiving the claimed structure, wherein the recess corresponds in one of shape and size to the structure, as also required by each of independent claims 34, 40, 41, and 42. Accordingly, Fleischman et al. fails to disclose, teach, or otherwise suggest each and every limitation of independent claims 34, 40, 41, and 42.

For at least these reasons, Applicant respectfully requests the reconsideration and withdrawal of the Section 102(e) rejection of claims 34-36, 38-45, 47-49, and 58-60 over Fleischman et al.

35 U.S.C. § 102(e) Rejection Over Melvin

Applicant respectfully traverses the Section 102(e) rejection of claims 34-36, 38-45, 47-49, 52-55, 57, 59, and 60 over Melvin.

Melvin discloses a mechanical activator device that includes portions internal to the heart and portions external to the heart. As best shown in Fig. 2 of Melvin, the internal portions include an internal stint 52 that comprises a septal splint 54, a ring 56, and a ring 58. The septal splint 54 contacts and supports the septum outside of the left ventricle, and includes one or more strands of sutures 55 affixed to a triangularly shaped frame 53. See col. 4, lines 61-66 and col. 5, lines 6-10. The rings 56 and 58 connect to the septal splint 54 and are placed adjacent valves in the left atrium and left ventricle, respectively. The stint 52 connects to the external portion of the device via cords 86 that extend through the heart wall. See col. 8, lines 32-34. Melvin further discloses that the external portion includes a yoke 70 and an activator 74, as shown in, for example, Fig. 5A. The yoke 70 includes an apical portion 70a and a base portion 70b. See, for example, col. 6, lines 11-17.

In the Office Action, the Examiner alleges that cords 86, frame 53, ring 58, and splint 54, collectively, correspond to the claimed connector. See Office Action at page 5. Furthermore, the Examiner alleges that the apical and base portions 70a and 70b of yoke 70 correspond to the claimed plurality of members. *Id.* Applicant respectfully disagrees with these allegations. Even assuming that cords 86, frame 53, ring 58, splint 54, and apical and base portions 70a and 70b of yoke 70 and structure of the disclosed Melvin device meet the other recitations of claims 34, 40, 41, and 42, which Applicant does not concede, Melvin fails to disclose, teach, or otherwise, suggest that the combination of cords 86, frame 53, ring 58, and splint 54 includes a structure for

connecting the combination to one of the portions 70a or 70b, wherein the structure includes a cross-sectional dimension that is different than a cross-sectional dimension of the combination, as required by each of independent claims 34, 40, 41, and 42.

Additionally, Melvin does not disclose, teach, or otherwise suggest that one of the apical and base portions 70a and 70b of yoke 70 includes a recess for receiving the claimed structure, wherein the recess corresponds in one of shape and size to the structure, as also required by each of independent claims 34, 40, 41, and 42. Accordingly, Melvin fails to disclose, teach, or otherwise suggest each and every limitation of independent claims 34, 40, 41, and 42.

For at least these reasons, Applicant respectfully requests the reconsideration and withdrawal of the Section 102(e) rejection of claims 34-36, 38-45, 47-49, 52-55, 57, 59, and 60 over Melvin.

Finally, because claim 42 is patentable over each of O'Connor, Fleischman et al., and Melvin for the reasons explained above, Applicant respectfully requests the rejoinder and allowance of withdrawn claims 50-51, since these claims depend from claim 42.

35 U.S.C. § 102(b) or § 103(a) Rejection of Claim 55

In the Office Action, the Examiner rejected claim 55 under 35 U.S.C. § 102(b) as allegedly being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as allegedly being obvious over O'Connor (or claim 57 of Fleishman et al.). Even assuming the Examiner's allegations are correct, which Applicant does not concede, claim 55 depends from claim 42 and is allowable for at least the same reasons as claim

42. Accordingly, Applicant respectfully requests the reconsideration and withdrawal of the Examiner's rejection of claim 55.

New Claims 80-91

In addition to being allowable for at least the same reasons as claims 34, 40, 41, and 42, each of new claims 80-91 include limitations drawn to subject matter that the applied prior art, alone or in combination, fails to disclose, teach, or otherwise suggest. For example, claims 80-83 specify that the claimed "structure is a ball." Additionally, claims 84, 86, 88, and 90 require the claimed recess to include "an opening configured to receive the [claimed] connector." Furthermore, claims 85, 87, 89, and 91 require the claimed opening to be "smaller than the [claimed] structure."

For at least these reasons, Applicant respectfully submits that new claims 80-91 are in condition for allowance.

Conclusion

The Office Action contains characterizations of the claims and the related art with which Applicant does not necessarily agree. Unless expressly noted otherwise, Applicant declines to subscribe to any statement or characterization in the Office Action.

In discussing the specification, claims, and/or drawings in this Amendment, it is to be understood that Applicant is in no way intending to limit the scope of the claims to an exemplary embodiment described in the specification or abstract and/or shown in the drawings. Rather, Applicant is entitled to have the claims interpreted broadly, to the maximum extent permitted by statute, regulation, and applicable case law.

Applicant respectfully requests that this Amendment under 37 C.F.R. § 1.116 be entered by the Examiner, placing claims 34-36, 38-45, 47-55, 57, 59-60, and 80-91 in condition for allowance. Applicant submits that the proposed amendments of claims 34 and 40-42, and the addition of new claims 80-91, do not raise new issues or necessitate the undertaking of any additional search of the art by the Examiner. Therefore, this Amendment should allow for immediate action by the Examiner.

Furthermore, Applicant respectfully points out that the final action by the Examiner presented some new arguments as to the application of the art against Applicant's invention. It is respectfully submitted that the entering of this Amendment would allow Applicant to reply to the final rejections and place the application in condition for allowance.

Finally, Applicant submits that the entry of this Amendment would place the application in better form for appeal, should the Examiner dispute the patentability of the pending claims.

If the Examiner wishes to discuss this application, he is invited to contact the undersigned at (202) 408-4221.


In view of the foregoing amendments and remarks, Applicant respectfully submits that this claimed invention, as amended, is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicant therefore requests the entry of this Amendment, the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this Amendment, and
charge any required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

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By: 
Dinesh N. Melwani
Reg. No. 60,670